

Application No. 09/965,697  
Amendment dated September 14, 2004  
Reply to Office Action dated May 14, 2004

### REMARKS

Claims 1-20 are pending in this application. The Examiner previously indicated that claims 1-20 are generic to a plurality of disclosed patentably distinct species of multiple inducible gene modulation systems, comprising ligand binding domain, DNA binding domain, and transactivation domain, and applicant is thus required under 35 U.S.C. § 121 to elect a single disclosed multiple inducible gene modulation system for examination purposes.

In reply, and solely to be responsive to the Examiner's requirement to elect a single disclosed multiple modulation system, Applicants have provisionally elected, with traverse, Group I, claims 1-4, 9-12 and 16-20, drawn to multiple inducible gene modulation systems comprising a first gene modulation system comprising a first ligand binding domain (LBD) comprising a C/EcR LBD comprising a V96T/N119F substitution mutation, a second ligand binding domain comprising a chimeric RXR; a DNA binding domain (DBD) comprising a GAL4 DBD, a transactivation domain (AD) comprising a VP16 AD, and a response element (RE) comprising a GAL4 RE; a second gene modulation system comprising a first LBD comprising a C/EcR ligand binding domain comprising a A110P/T52V substitution mutation, a second LBD comprising a chimeric RXR, a DBD comprising a LexA DBD, a response element comprising a LexA RE, and a VP16 transactivation domain (AD).

However, Applicants respectfully submit that prosecution of the multiple inducible gene modulation systems, comprising ligand binding domains, DNA binding domains, and transactivation domains, of Group I in the present application is appropriate. Under Patent Office examining procedures, "[i]f the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions" (MPEP 803, Rev. 8, May 1988) (emphasis added). The plurality of multiple inducible gene modulation systems, comprising ligand binding domain, DNA binding domain, and transactivation domain, designated by the Examiner fail to define products with properties so distinct as to warrant separate examination and search.

Likewise, Applicants contend that it is a burden on the Applicants to choose or define only one specific multiple gene modulation system as the Applicants have identified [69 receptors and 247 ligands (69 x 247)=] 17,043 receptor-ligand

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combinations. Furthermore, the claims encompass multiple gene modulation systems, not just two. Applicants have also designed a triplex of orthogonal receptor-ligand pairs, and from the number of receptor-ligand combinations identified, it is possible to have even more multiple gene modulation systems operable within one cell, tissue or organism.

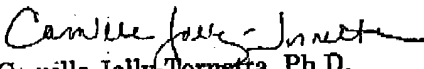
Accordingly, examination of the plurality of inducible gene modulation systems of the present claims involves a fundamental determination of the novelty of multiple inducible gene regulation systems. To the extent that this determination would be made, it is submitted that a preponderantly coextensive search would result. In particular, an exhaustive search for one gene modulation system comprising a DNA binding domain, ligand binding domain, and transactivation domain would encompass other inducible gene modulation systems comprising a DNA binding domain, ligand binding domain and transactivation domain.

Thus, Applicants submit that the search and examination of the plurality of multiple inducible gene regulation systems of the present application can be made without serious burden. Applicants respectfully submit that conjoint examination and inclusion of all of the multiple inducible gene regulation systems of the present application would not present an undue burden on the Examiner, and accordingly, withdrawal of this restriction or reconsideration is believed to be in order.

In the event that the restriction requirement is maintained, Applicants reserve the right to file divisional applications directed to the subject matter of the non-elected claims of Group II and additional multiple inducible gene regulation systems. If a telephone interview would be of assistance in advancing prosecution of this application, Applicants' agent invites the Examiner to contact her at (610) 650-8734 ext. 104.

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